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JAMES C. LYDON				
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ALEXANDRIA, VA 22314				
EXAMINER				
GOON, SCARLETT Y				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ADVISORY ACTION

This Office Action is in response to Applicants' Remarks after FINAL filed on 30 March 2009. No proposed amendment to the claims has been filed after FINAL.

Applicants' arguments, submitted 30 March 2009, with respect to the rejection of claims 13-21 under 35 USC § 103(a) as being unpatentable over U.S. Patent 6,451,849 B1 to Ahotupa *et al.*, in view of U.S. Patent No. 6, 559,168 B2 to Marfat *et al.*, have been fully considered but is not persuasive to overcome the prior art rejection of record. Specifically, Applicants argue that the cited combination of references fails to raise a *prima facie* case of obviousness against the claimed composition because one of ordinary skill in the art would not have a reasonable expectation of success regarding formation of a cyclodextrin inclusion complex with HMR. These arguments are not persuasive because the Marfat '168 patent teaches PDE4 inhibitors which include two disclosed lignan structures and further teach that in order to improve the stability of the pharmaceutical compositions, which include the PDE4 inhibitors, sequestering agents such as cyclodextrins can be used. The Marfat '168 patent reiterates what is well-known in the art regarding cyclodextrins, that they improve the stability of pharmaceutical compositions. Furthermore, within the art of cyclodextrins, it is common knowledge that they come in different ring sizes, have different solubilities, and different charges, as further reiterated in the Marfat '168 patent. Therefore, contrary to Applicants' argument, one would have been motivated to combine the teachings as the Marfat '168 patent suggests that cyclodextrins can be used in a pharmaceutical

composition to improve the stability of the composition, and one of ordinary skill in the art would have a reasonable expectation of success as the process in choice of cyclodextrins is common knowledge within the art, which depends on the different physical and chemical properties of the pharmaceutical compound and the cyclodextrin.

Thus, Applicants' arguments are not persuasive to overcome the prior art rejection of record in the Final Office Action dated 30 December 2008.

Applicants' arguments, submitted 30 March 2009, with respect to the rejection of claims 13, 17 and 21 under 35 USC § 102(e) as being unpatentable over PG Pub No. US2005/0169947 A1 by Korte *et al.*, have been fully considered and is persuasive because the effective reference date of the Korte *et al.* reference is 15 May 2003, which is after the priority date of the instant application, 29 August 2002, which is the filing date of the foreign priority document. Since the claim to foreign priority has been perfected, the Korte *et al.* reference does not qualify as prior art to the instant application.

These rejections are withdrawn.

Applicants' arguments, submitted 30 March 2009, with respect to the rejection of claims 14-16 and 18-20 under 35 USC § 103(a) as being unpatentable over PG Pub No. US2005/0169947 A1 by Korte *et al.*, as applied to claims 13, 17 and 21, further in view of U.S. Patent No. 6, 559,168 B2 to Marfat *et al.*, have been fully considered and is persuasive because the effective reference date of the Korte *et al.* reference is 15 May

2003, which is after the priority date of the instant application, 29 August 2002, which is the filing date of the foreign priority document. Since the claim to foreign priority has been perfected, the Korte *et al.* reference does not qualify as prior art to the instant application.

These rejections are withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

/SCARLETT GOON/
Examiner
Art Unit 1623